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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary	Application No.	Applicant(s)	
	10/788,906	GIROUARD ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,8-13,32-34,39-44 and 63-78* is/are pending in the application.

4a) Of the above claim(s) *4-7,14-31,35-38,45-62 and 79-148* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8-13,32-34,39-44 and 63-78* is/are rejected.

7)☒ Claim(s) *32,39 and 73* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/05 01/06 03/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-78), species VI, species D and species 1 in the reply filed on October 26, 2005 is acknowledged. The traversal of the Restriction Requirement is on the ground(s) that the inventions are closely related (see Applicant's Remarks page 21, lines 21-22). Although this may be correct, the Examiner explained in the Restriction Requirement of September 23, 2005 why the inventions are considered distinct and/or different inventions and in addition, the arguments are not found persuasive because Applicant has not pointed out why the Restriction Requirement was improper.

2. The traversal of the Restriction Requirement is also on the ground(s) that there is no undue burden on the Examiner (see Applicant's Remarks page 22, lines 4-12). This is not found persuasive because it is shown by the different subclasses of each group of inventions that the search for each invention is different. Also, for example, the search for the invention defined by group I is different from the search for the invention defined for group II because the search for the invention defined by group II requires the Examiner to search for a method which detects a predetermined cardiac condition while the search for the invention defined by group I does not require such details. In addition, as another example, the search for the invention defined by group II is different from the search for the invention defined by group III because the search for the invention defined by group III requires the Examiner to search for a method that includes preparing an implantable device effective to control expression of at least one exogenously

introduced expression cassette while the search for the invention defined by group II does not require such details.

3. The traversal of the requirement for an Election of Species is on the ground(s) that the disclosed species have a disclosed relationship (see Applicant's Remarks page 22, lines 19-25). This is not found persuasive because where an application includes claims directed to different embodiments or species that could fall within the scope of a generic claim, restriction between the species is proper if the species are independent and/or distinct. In the instant case, for example, a method/device with a gene regulatory signal delivery device that comprises an electromagnetic field generator, which emits an electromagnetic field, is independent and patentably distinct from a method/device with a gene regulatory signal delivery device that comprises a thermal radiator, which emits thermal energy. In addition, Applicant has not submitted evidence or identified that the each species defined in the Election of September 23, 2005 overlap in scope and/or are obvious variants over each other.

4. Applicant ascertains that claims 1-78 read on the elected species VI, D and 1, however this is incorrect. Claims 1-78 read on all species I-VI, all species A-F and all species 1-9. For example, claim 4 reads "The system of claim 1, wherein the gene regulatory signal delivery device comprises a light emitter which emits a light having a predetermined wavelength and energy" and is therefore not embodied by the elected species VI "wherein the gene regulatory signal deliver device comprises an electromagnetic field generator which emits an electromagnetic field have a predetermined frequency". The distinguishing features of the different species (in this example) are directed to different kinds of energy used for the gene regulatory signal. The Examiner is prosecuting claims 1-3, 8-13, 32-34, 39-44 and 63-78 as

claims being drawn to elected invention (defined by Group I) and the elected single species VI, single species D and single species 1. The Examiner considers Claims 4-7, 14-31, 35-38, 45-62 and 79-148 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and/or inventions, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on October 26, 2005, January 10, 2006 and March 3, 2006 have been acknowledged and are being considered by the Examiner.

Claim Objections

6. Claims 32 and 39 are objected to because of the following informalities: there appears to be a typographical error present that affects both claims. The Examiner suggests changing "the event detector" presented in line 7 of Claim 32 to read "an event detector" to avoid an antecedent basis problem. If this change is made, the Examiner further suggest changing the first two lines Claim 39 to read "the system of claim 32, wherein the event detector detects the predetermined cardiac event from the sensed". Appropriate correction is required.

7. Claim 73 is objected to because of the following informalities: there appears to be a typographical error in the claim. Currently, the claim depends from Claim 72, however, the limitations presented seem to conflict with the limitations of Claim 72. The Examiner suggests changing Claim 73 to depend from Claim 71 instead and is prosecuting the application as such. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2, 8, 13, 32-33, 39, 44, 63, 67, 71 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Soykan et al. (U.S. 2001/0000802) (herein Soykan). As to Claim 1, Soykan discloses a system 51 (see Soykan Fig. 5) comprising a subcutaneous electrode array, read as a sensor to sense a physiological signal (i.e. a pseudo-surface ECG) indicative of a predetermined cardiac condition (i.e. ischemia) (see Soykan page 10, paragraph 86) and a stent, read as a gene regulatory delivery device 18 that emits a regulatory signal (i.e. electrical, mechanical, acoustic, thermal, chemical or combinations thereof) which directly or indirectly regulates a regulatable transcriptional control element releasably located in variety of drug delivery mechanisms (see Soykan page 4, paragraphs 25-28, page 5, paragraph 43, page 6, paragraphs 44-46, page 8, paragraphs 64 and 69-72 and page 10, paragraph 88). Soykan further discloses controller 92 coupled to the sensor (via sense amplifier 53) and the gene regulatory signal delivery device 18 (via antenna-lead 24) where the controller 92 is adapted to control emission of the regulatory signal based on the sensed physiological signal (see Soykan Fig. 2, page 2, paragraphs 9-11, page 3, paragraphs 12-15, page 4, paragraphs 27-28, page 8, paragraph 69, page 9, paragraphs 82-84 and page 10, paragraph 88).

10. As to Claim 2, Soykan discloses that the controller 92 of stimulation device 22 produces a radio frequency signal 26 using antenna-lead 24 which is then received by gene regulatory

delivery device 18. The gene regulatory delivery device 18 converts the magnetic field into an electrical signal, which is then used to create an electric field to trigger the release of the transcriptional control element (i.e. promoter or the like) (see Soykan page 2, paragraph 10, page 4, paragraph 28 and page 10, paragraph 88).

11. As to Claim 8, Soykan discloses that the system 51 further comprises circuitry, read as an event detector 57 to detect the predetermined cardiac condition (i.e. ischemia) from the sensed physiological signal (i.e. a pseudo-surface ECG) where the controller 92 of stimulation device 22 is adapted to control the emission of the regulatory signal in response to a detection of the predetermined cardiac event (i.e. onset of ischemia represented by abnormal morphology) (see Soykan Fig. 2, page 3, paragraphs 22-24, page 4, paragraphs 27-28, page 8, paragraph 69, page 9, paragraphs 82-84 and page 10, paragraph 88).

12. As to Claim 13, the sensor of Soykan senses a physiological signal (i.e. a pseudo-surface ECG) indicative of ischemia and the event detector 57 inherently comprises an ischemia detector since it is capable of detecting ischemia from the sensed ECG signal (see Soykan Fig. 2, page 3, paragraphs 22-24, page 4, paragraphs 27-28, page 8, paragraph 69, page 9, paragraphs 82-84 and page 10, paragraph 88).

13. As to Claim 32, Soykan discloses a system 51 (see Soykan Fig. 5) comprising an implantable stimulation device, read as an implantable medical device system 22 including a subcutaneous electrode array, read as a sensor to sense a physiological signal (i.e. a pseudo-surface ECG) indicative of a predetermined cardiac condition (i.e. ischemia) (see Soykan page 10, paragraph 86), a RF transmitter and receiver unit, read as an implant telemetry module 55 to receive an external command from an external programming device (see Soykan Fig. 2, page 9,

paragraphs 77-78 and 81), and a stent, read as a gene regulatory delivery device 18 that emits a regulatory signal (i.e. electrical, mechanical, acoustic, thermal, chemical or combinations thereof) which directly or indirectly regulates a regulatable transcriptional control element releasably located in variety of drug delivery mechanisms (see Soykan page 4, paragraphs 25-28, page 5, paragraph 43, page 6, paragraphs 44-46, page 8, paragraphs 64 and 69-72 and page 10, paragraph 88). Soykan discloses that the system 51 further comprises circuitry, read as an event detector 57 coupled to controller 92 to detect the predetermined cardiac condition (i.e. ischemia) from the sensed physiological signal (i.e. a pseudo-surface ECG) where the controller 92 of stimulation device 22 is adapted to control the emission of the regulatory signal in response to a detection of the predetermined cardiac event (i.e. onset of ischemia represented by abnormal morphology) via output pulse generator, read as a gene expression control module 74 (see Soykan Fig. 2, page 3, paragraphs 22-24, page 4, paragraphs 27-28, page 8, paragraph 69, page 9, paragraphs 82-84 and page 10, paragraph 88). Soykan further disclose that alternatively the controller 92, which is also coupled to the implant telemetry module 55 (see Soykan Fig. 2), may receive an external command to control the emission of the regulatory signal via the gene expression control module 74 (see Soykan page 4, paragraph 26). Soykan also discloses that the eternal programming device is a microprocessor device which provides a series of encoded signals to stimulation device 22 by means of a programming head, read as an external telemetry module which transmits radio frequency encoded signals according to a telemetry system or an external patient initiated command to the implant telemetry module 55 (see Soykan page 4, paragraph 26 and page 9, paragraph 78).

14. As to Claim 33, Soykan discloses that the controller 92 of stimulation device 22 produces a radio frequency signal 26 using antenna-lead 24 which is then received by gene regulatory delivery device 18. The gene regulatory delivery device 18 then converts the magnetic field into an electrical signal, which is then used to create an electric field to trigger the release of the transcriptional control element (i.e. promoter or the like) (see Soykan page 2, paragraph 10, page 4, paragraph 28 and page 10, paragraph 88).

15. As to Claim 39, Soykan discloses that the event detector 57 detects the predetermined cardiac condition (i.e. ischemia) from the sensed physiological signal (i.e. a pseudo-surface ECG) and that the controller 92 of stimulation device 22 is adapted to control the emission of the regulatory signal in response to a detection of the predetermined cardiac event (i.e. onset of ischemia represented by abnormal morphology) (see Soykan Fig. 2, page 3, paragraphs 22-24, page 4, paragraphs 27-28, page 8, paragraph 69, page 9, paragraphs 82-84 and page 10, paragraph 88).

16. As to Claim 44, the sensor of Soykan senses a physiological signal (i.e. a pseudo-surface ECG) indicative of ischemia and the event detector 57 inherently comprises an ischemia detector since it is capable of detecting ischemia from the sensed ECG signal (see Soykan Fig. 2, page 3, paragraphs 22-24, page 4, paragraphs 27-28, page 8, paragraph 69, page 9, paragraphs 82-84 and page 10, paragraph 88).

17. As to Claim 63, Soykan discloses the current implantable pulse generators, that are well known in the art, may be modified to stimulate the drug-eluting cells in accordance with the teachings of the implantable medical device system 22 such as a wide variety of microprocessor-based implantable pacemakers (see Soykan page 9, paragraph 76). It is inherent that the

controllers of such pacemakers would provide control of pacing circuitry in conjunction with the emission of the regulatory signal.

18. As to Claim 67, Soykan discloses the current implantable pulse generators, that are well known in the art, may be modified to stimulate the drug-eluting cells in accordance with the teachings of the implantable medical device system 22 such as a wide variety of microprocessor-based implantable defibrillators or cardiovertors (see Soykan page 9, paragraph 76). It is inherent that the controllers of such defibrillators or cardiovertors would provide control of defibrillation/cardioversion circuitry in conjunction with the emission of the regulatory signal.

19. As to Claim 71, Soykan discloses that the implantable medical device system 22 comprises a hermetically sealed enclosure, read as a can to house at least the implant controller 92 and the implant telemetry module 55 (see Soykan Fig. 2 and page 9, paragraph 77).

20. As to Claim 73, Soykan discloses that the subcutaneous electrode array, read as a sensor to sense a physiological signal (i.e. a pseudo-surface ECG) indicative of a predetermined cardiac condition (i.e. ischemia) is external to the hermetically sealed can (see Soykan Fig. 2 and page 10, paragraph 86).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. Claims 3 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan in view of Hamm et al. (U.S. 2004/0030379) (herein Hamm). Soykan discloses that the controller 92 of stimulation device 22 produces a radio frequency signal 26 using antenna-lead 24 which is then received by gene regulatory delivery device 18. The gene regulatory delivery device 18 converts the magnetic field into an electrical signal, which is then used to create an electric field to trigger the release of the transcriptional control element (i.e. promoter or the like) (see Soykan page 2, paragraph 10, page 4, paragraph 28 and page 10, paragraph 88). It is inherent that not all of the magnetic field is transferred into a pure electrical signal and that some electromagnetic field is left/applied for transduction. Soykan discloses the claimed invention as discussed above except that the amount of electromagnetic field is not predetermined.

Hamm, however, discloses an on demand medical device that includes an electromagnetic field generator for facilitation of transduction to directly or indirectly regulate a regulatable transcriptional control element (see Hamm Abstract, page 1, paragraphs 4-7, page 2, paragraphs 22 and 26 and page 3, paragraphs 26-27). Hamm also discloses that the gene regulatory signal delivery device may be a stent or the like and is thus synonymous with the invention of Soykan (see Hamm page 4, paragraphs 39-40). Hamm further discloses that one skilled in the art can determine the excitation source frequency of the electromagnetic source depending on the size of the molecules being used for delivery and/or the compositions of the gene regulatory signal delivery devices being used (see Hamm page 7, paragraph 86). Therefore, it would have been obvious to one having ordinary skill in the art to modify the system of Soykan in view of Hamm to include an electromagnetic field generator with a generation of a

predetermined frequency for the electromagnetic field to tailor the speed of transduction for the particular promoter/transcriptional control element being used in the invention.

23. Claims 9 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan in view of Darvish et al. (U.S. 2002/0183686) (herein Darvish). Soykan discloses the claimed invention as discussed above except the event detector 57 is not specified to comprise an event parameter generator to produce one or more condition parameters related to at least one of a type and a degree of the predetermined cardiac condition and the controller 92 is not specified to comprise a regulatory signal parameter controller to quantitatively control the emission of the regulatory signal based on the one or more condition parameters.

Darvish, however, discloses a drug delivery device for targeted release of a molecule (i.e. genetic material) carried in a circulating reservoir comprising at least one electrode 804 and a controller 810 adapted to electrify the electrode 804 with at least one electric field to electroporation or electrical transportation of the molecule. Darvish further discloses that the device is used to control the type, timing and/or dosage of molecule to be applied (see Darvish Abstract, page 1, paragraphs 7-10, page 2, paragraphs 16 and 18-19 and page 3, paragraphs 22-30). Darvish further discloses that the apparatus 100 may comprise a sensor 108 for measuring a physiological parameter (i.e. of the heart 102) and that the controller (i.e. CPU) 122 of the apparatus 100 uses the measurement from the sensor input 130 for determining the parameters of the electrification (see Darvish page 4, paragraph 45 and page 7, paragraph 105). In addition the apparatus 100 of Darvish further includes a watchdog, which watches over the heart to assure that the heart does not, as a result of the treatment, exceed operational or functional parameters defined by the heart's activity. Specifically, the watchdog is implemented as a separate

processor/sensor, which is involved in a feedback loop to stop or modify application of the electric field, read as quantitatively control the emission of a regulatory signal in response to a sensed arrhythmia or ventricular tachycardia, read as one or more condition parameters relating to a type of a predetermined cardiac condition (see Darvish page 7, paragraph 105-108, page 8, paragraph 109, page 13, paragraphs 182-186, page 15, paragraphs 216-217 and page 17, paragraph 243). Darvish discloses that the application regimen may be varied in response to needs of the excitatory tissue (see Darvish page 2, paragraph 19). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the event detector of Soykan in view of Darvish to comprise an event parameter generator to produce one or more condition parameters related to at least one of a type and a degree of the predetermined cardiac condition and to modify the controller of Soykan in view of Darvish to comprise a regulatory signal parameter controller to quantitatively control the emission of the regulatory signal based on the one or more condition parameters to allow the application regimen to be varied in response to needs of the excitatory tissue.

24. Claims 10-12 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan in view of Donahue et al. (U.S. 2002/0155101) (herein Donahue). Soykan discloses system 51 (see Soykan Fig. 5) comprising a subcutaneous electrode array, read as a sensor to sense a physiological signal (i.e. a pseudo-surface ECG) indicative of a predetermined cardiac condition (i.e. ischemia). It is inherent that the stimulation device 22 comprises an electrogram sensing circuit since it sensed an electrogram from the output the subcutaneous electrode array, read as a sensor. Soykan discloses the claimed invention as discussed above except that the event detector 57 doe not comprise an atrial or ventricular fibrillation detector.

Donahue, however, teaches that it is well known in the art to use a regulatable transcriptional control element in cardiac gene therapy for treatment of any of the following: sinus bradycardia, sinus tachycardia, atrial tachycardia, atrial fibrillation, atrial flutter, atrioventricular nodal block, atrioventricular node reentry tachycardia, atrioventricular reciprocating tachycardia, ventricular tachycardia or ventricular fibrillation (see Donahue page 7, paragraph 94). Donahue also discloses that practice of the invention is broadly compatible with one or a combination of different administration systems (see Donahue page 7, paragraph 88) for more effective and flexible anti-arrhythmic therapies by providing therapeutic methods for administering one or more therapeutic polynucleotides to the heart under conditions sufficient to modulate (increase or decrease) at least one heart electrical property. Donahue further discloses that the invention modulates heart electrical conduction, reconfigures all or part of the cardiac action potential (AP) and reduces or avoids significant disruption of normal electrical function (see Donahue page 2, paragraph 14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Soykan in view of Donahue to administer the gene therapy upon detection of an atrial fibrillation or ventricular fibrillation to better the invention's capabilities of eliminating a wide variety of predetermined cardiac conditions.

25. Claims 64 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan in view of Shelton et al. (U.S. 5,312,453) (herein Shelton). Applicant differs from Soykan in that the delivery of pacing pulses or cardioversion/defibrillation shocks is based on at least the external command. The Examiner considers the use of external commands to control pacing/cardioversion/defibrillation delivery to be conventional and well known in the art with

Shelton being but one example. Specifically, Soykan discloses that the implantable medical device system 22 disclosed may be incorporated into the rate-responsive pacemaker of Shelton (see Soykan page 9, paragraph 76).

26. Claims 69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan in view of Bardy (U.S. 5,314,430). Applicant differs from Soykan in that the device comprises at least one atrial defibrillation lead coupled to the defibrillation circuit to delivery the defibrillation shocks to one or more atria and the defibrillation control module comprises an atrial defibrillation control module. Applicant also differs from Soykan in that the device comprises at least one ventricular defibrillation lead coupled to the defibrillation circuit to delivery the defibrillation shocks to one or more ventricles and the defibrillation control module comprises an ventricular defibrillation control module. The Examiner considers the use or atrial/ventricular leads coupled to atrial/defibrillation control modules in a implantable pulse generator/defibrillator to be conventional and well known in the art for the defibrillation of both that atria and ventricles with Bardy being but one example. Specifically, Soykan discloses that the implantable medical device system 22 disclosed may be incorporated within the defibrillator of Bardy (see Soykan page 9, paragraph 76).

27. Claims 65-66 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan. As to Claim 65, Soykan discloses the claimed invention but does not expressly discloses an embodiment where the implantable medical device system 22 further comprises a cardiac resynchronization therapy (CRT) circuit coupled to the implant controller and wherein the implant controller includes a CRT control module adapted to control delivery of CRT in conjunction with the emission of the regulatory signal. It would have been an obvious matter of

design choice to a person of ordinary skill in the art to modify the system as taught by Soykan with a CRT circuit coupled to the implant controller where the implant controller includes a CRT control module adapted to control delivery of CRT in conjunction with the emission of the regulatory signal, because Applicant has not disclosed that such modification provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the pacing circuitry, cardioversion circuitry or defibrillation capabilities as taught by Soykan, because it provides suitable integration of the invention with most current implantable pulse generators of the art and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Soykan.

Therefore, it would have been an obvious matter of design choice to modify Soykan to obtain the invention as specified in the claim(s).

28. As to Claim 66, Soykan discloses the claimed invention but does not expressly discloses an embodiment where the implantable medical device system 22 further comprises a remodeling control (RCT) therapy circuit coupled to the implant controller and wherein the implant controller includes a RCT control module adapted to control delivery of RCT in conjunction with the emission of the regulatory signal. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system as taught by Soykan with a RCT circuit coupled to the implant controller where the implant controller includes a RCT control module adapted to control delivery of RCT in conjunction with the emission of the regulatory signal, because Applicant has not disclosed that such modification provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore,

would have expected Applicant's invention to perform equally well with the pacing circuitry, cardioversion circuitry or defibrillation capabilities as taught by Soykan, because it provides suitable integration of the invention with most current implantable pulse generators of the art and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Soykan.

Therefore, it would have been an obvious matter of design choice to modify Soykan to obtain the invention as specified in the claim(s).

29. As to Claim 72, Soykan discloses the claimed invention but does not expressly disclose an embodiment where hermetically sealed can further houses the sensor. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system as taught by Soykan with the sensor within the can of the implantable medical device system 22, because Applicant has not disclosed that such a location for the sensor provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the subcutaneous electrode array, read as a sensor, which is not located within the can of the device as taught by Soykan, because it provides suitable means for detecting a pseudo-surface ECG signal to be input to the device for event detection and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Soykan.

Therefore, it would have been an obvious matter of design choice to modify Soykan to obtain the invention as specified in the claim(s).

30. Claims 74-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan in view of Nelson et al. (U.S. 2002/0072785). As to Claim 74, Soykan discloses that the analog

electrogram of the patient's electrical heart activity may be uploaded to the external programming device but does not expressly disclose that the electrogram is displayed (see Soykan page 7, paragraph 83). Soykan discloses the claimed invention as discussed above except that the external system does not comprise a presentation device to present the sensed physiological signal or a user input to receive the external command. The Examiner considers the use of a presentation device to present the sensed physiological signal, such as an external device including a display and a user input to receive the external command to be conventional and well known in the art with Nelson being but one example (see Nelson page 7, paragraph 58).

31. As to Claim 75, Soykan discloses that the external device is an external programmer (see Soykan page 9, paragraphs 77-78).

32. As to Claims 76-78, Soykan discloses that the external system comprises an advanced patient management system including an external device wirelessly coupled to the implantable medical device system via telemetry (i.e. the external programmer). Soykan discloses the claimed invention as discussed above except that it is not specified that the advanced patient management system also includes a remote device to provide access to the implantable medical device system from a distant location and a network connecting the external device and the remote device. The Examiner considers the use of a remote device with a network to be conventional and well known in the art of external programming for implantable medical devices with Nelson being but one example (see Nelson Abstract, Fig. 1, page 1, paragraph 6 and page 4, paragraphs 28-32).

Double Patenting

33. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

34. Claims 1, 8-10, 13, 32, 39-41, 44, 63-66 and 71-78 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-10, 12-18, 21-24 and 34-40 of copending Application No. 10/862,716. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35. Claims 1-3, 8-13, 32-34, 39-44 and 63-78 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 28-42 of copending Application No. 10/890,825. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof. Specifically, all the limitations claimed in the current application are expressly presented in claims 1-6 and 28-42 of copending Application No. 10/890,825.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

36. Claims 1-3, 8-10, 13, 32-34, 39-41 and 71-75 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 13 and 15-18 of copending Application No. 11/220,397. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

37. Claims 1-3, 8-9, 13, 32-34, 39-40, 44, 63-64 and 71-75 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 11-13 and 16-17 of copending Application No. 11/276,077. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

38. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

39. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 03/27/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766